

USAWC STRATEGY RESEARCH PROJECT

THE CASE FOR “FORCED” HEALTH PROTECTION

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ABSTRACT

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In the era following Desert Shield/Desert Storm veterans suffering from what has been dubbed "Gulf War Illness" have led many to believe that DoD's force health protection measures did more harm than good. It is this legacy, when added to similar military health related problems from other eras, that DoD was saddled with when the Secretary of Defense directed force-wide immunization with the anthrax vaccine in 1999. From the start, this force health protection policy, executed as the Anthrax Vaccine Immunization Program (AVIP), suffered from lack of trust between military leaders and the service member they led, an absence of a reliable source of vaccine, an inability to win the information campaign, and politicization of the program by the Congress. Despite all these issues, the AVIP remained the best protection for military personnel facing a real battlefield biological threat. While court challenges to stop the AVIP are still on-going, DoD must stay the course and never concede that force health protection should be a discretionary choice of each individual service member. At the same time, DoD must seek funding for continued research for a better anthrax vaccine as well as a more reliable source for future vaccines.

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THE CASE FOR "FORCED" HEALTH PROTECTION

It is the responsibility of commanders at all levels during war to bring the necessary amount of combat power to bear on the enemy at the decisive point in time and place to best accomplish the military mission. Commanders must not only build combat power but also preserve it in order to deliver it decisively on the battlefield. An important aspect of this is protecting the force during all phases of the campaign.¹ In fact, force protection has become in recent military endeavors the number one barometer of success, or, said another way, the lack of force protection has served as the number one measure of political failure.² A necessary component of force protection is the physical health of Soldiers, Sailors, Airmen, and Marines. Deployed service members who succumb to battlefield illnesses diminish the combat power of the fighting force. It, therefore, follows that protecting the health of the deployed force is as important as other aspects of force protection.

This paper proposes that force health protection is critical to the ability of today's United States military to defend the homeland and fight and win the Nation's wars. It is important enough that health protection cannot be left to the discretion of each service member. In this respect, involuntary or "forced" health protection measures must remain as one tool available to military leaders. The purpose of this paper is to consider the rationale for forced health protection and address strategic and legal implications that the military has faced and will likely continue to face. As a method of addressing these issues, this paper will use the Anthrax Vaccine Immunization Program (AVIP) as a case study to bring issues to life and to provide a current perspective on an important, but controversial health protection policy.

HISTORICAL CONTEXT

In response to a perceived threat to deployed military forces of exposure to weaponized anthrax, Secretary of Defense William Cohen announced on December 15, 1997, his plan to counteract the threat and protect the force through immunization of all military personnel.³ The Secretary made his intent and the reasons for it clear when he said, "This is a force protection issue. To be effective, medical force protection must be comprehensive, well documented, and consistent. I have instructed the military to put such a program in place."⁴ Deputy Secretary of Defense John Hamre later explained the scope of the new policy by saying, "Our goal is to vaccinate everybody in the force so they will be ready to deploy anywhere, anytime. This is an important new dimension to overall force protection. The anthrax vaccination will join other immunizations we already give everyone in the military."⁵

On May 18, 1998, after being satisfied that the conditions he set for implementation had been met, Secretary Cohen officially signed the policy for “Implementation of the Anthrax Vaccine Program for the Total Force.”⁶ In this document, the Secretary made it clear that his action in directing an anthrax vaccination effort was in support of a recommendation by the Chairman and the Joint Chiefs.⁷ This document also served to designate the Army as the Executive Agent for the program.⁸ As a result of this designation, the Army created the Anthrax Vaccine Immunization Program (AVIP) Agency under the purview of the Army Surgeon General.⁹ Thereafter, AVIP began securing available stockpiles of vaccine, seeking a ready source of vaccine from a commercial source, creating educational materials for leaders and service members, establishing medical surveillance systems, and overseeing the execution plans prepared by the other Services. All in all, AVIP did everything that one would expect of trained and professional military planners in order to ensure program success. The problem the program encountered, however, was not so much what the AVIP was doing, but instead was tied, in part, to what had happened in the past. The issue can be reduced to one word: Trust.

THE LEGACY OF THE PAST

Before considering specific issues about the anthrax vaccine, suffice at this point to say that prior to the first Gulf War in 1990, only about 68,000 doses of anthrax vaccine had been administered, starting in 1974, primarily to mill workers, persons who handled potentially infected livestock, veterinarians, and people who worked with imported animal hides, hairs or bones.¹⁰ Consequently, the public-at-large was very unfamiliar with the anthrax vaccine, unlike other vaccines—such as the influenza vaccine—that a majority of Americans had taken at one time or another. As a result, the absence of exposure to a network of family or friends that had taken the anthrax vaccine in the past made this military-wide immunization program ripe for barracks rumors (fueled by the Internet) and urban legends. AVIP and leaders throughout the Department of Defense (DoD) and the Services found themselves engaged in a protracted information campaign to dispel what were perceived as falsehoods, misapprehensions, and paranoia about the vaccine. Despite a plethora of medical and scientific evidence to support the safety and efficacy of the vaccine, many service members, their family members, their supporters, and Members of Congress expressed grave doubts, often accusing the military of using service members as guinea pigs.

Why would DoD and the Services as institutions fail to gain the trust of the men and women who make up the most educated fighting force in the world? Paramount in long-lasting successful organizations is a level of trust between the leaders and the led. In no institution is

this more critical than in the military where those led entrust themselves to leaders in life and death situations. Unfortunately, the military's record in health protection of service members has been, in hindsight, less than stellar.

Of most recent note are those ailments and illnesses suffered by veterans of Desert Shield/Desert Storm over the last twelve years now known as Gulf War Illness Syndrome. The most commonly reported physical symptoms include: "fatigue, headaches, joint pains, skin rash, shortness of breath, sleep disturbances, difficulty communicating and forgetfulness."¹¹ Many other veterans of the first Gulf War, some in disproportional numbers to the general public, have been diagnosed with medial diseases including amyotrophic lateral sclerosis (ALS), various malignant cancers, connective tissue diseases, and immunologic abnormalities.¹² Determining specific causes for these medical and physical problems has proven problematic for the government.¹³ The bottom line is that despite a decade of research the reasons for Gulf War Illness Syndrome remain a medical mystery with many veterans still suffering.¹⁴

For many veterans of the Vietnam War, the significant health problems from exposure to an herbicide known as Agent Orange (a defoliant sprayed in jungle areas usually in proximity to military base camps) did not come to light until well after returning from the war. Between 1965 and 1970 more than 19 million gallons of Agent Orange were sprayed throughout Vietnam.¹⁵ Beginning in the 1970's, some Vietnam veterans became convinced that their health problems were related to exposure to Agent Orange.¹⁶ Subsequent research unveiled that an ingredient in the herbicide, TCDD (dioxin), caused illness in laboratory animals.¹⁷ The Department of Veterans Affairs (VA), because of Congressional involvement, now presumes Agent Orange exposure for Vietnam veterans for the purpose of providing health care for an ever-expanding host of diseases "associated" with exposure to Agent Orange.¹⁸ As is true of the first Gulf War, there is no credible evidence that the government exposed its troops in Vietnam to Agent Orange knowing that such exposure might lead to long-term medical problems. Unfortunately, the failure to have discerned potential health risks beforehand does nothing to engender trust and confidence when service members question health protection policies today.

Another Cold War era operation raised health issues among sailors who were knowingly or unknowingly part of Project SHAD (Shipboard Hazard and Defense) tests conducted at sea between 1962 and 1973.¹⁹ These veterans now claim they were exposed to toxic substances to their health detriment. Project SHAD was designed to test American warships' vulnerabilities in the event of chemical or biological attacks.²⁰ Most of these tests have been kept classified over the years further contributing to speculation that sailors were intentionally exposed to chemical or biological agents. Not until September 2000, at the request of the VA, did DoD begin to de-

classify and report publicly what happened during 46 known tests.²¹ While DoD maintains that there is no connection between Project SHAD testing and later illnesses in veterans who served on those ships, many of those veterans remain unconvinced.

One final example from the past that continues to undermine trust in government to safeguard the health of service members are those haunting black and white film images of soldiers in the Nevada desert facing a mushroom cloud following the detonation of an atomic explosion. Records now tell us that some 200,000 people, many of them soldiers, were present as part of atomic experiments in the 1950s.²² By all accounts, DoD was focused on short-term risks, not long-term health implications to participants. A lack of record keeping regarding specific radiation exposure has made it difficult for the government today to pinpoint radiation exposure for participants. Nevertheless, it is clear that certain diseases, such as leukemia, may be occurring in these “atomic veterans” at rates disproportional to the general population.²³ The “atomic veterans” represent yet another generation of service members who relied on representations from their government that they would be “safe”²⁴

The debilitating and, in some cases, fatal effects from the foregoing “programs” cause many to question whether the government can be trusted to safeguard the health of its service members. It matters not to today’s service members whether previous government or military decisions knowingly exposed service members to potential health risks or simply did so out of well-intentioned ignorance. The legacy of the past prompts service members facing an anthrax shot today to ask, “How can you be certain that this vaccine is safe if your predecessors thought they knew for sure then what they were doing was safe (and were wrong)? “

THE THREAT

The first stanza of AVIP’s education mantra begins with the assertion that the threat of anthrax exposure is real.²⁵ Certainly, the absence of a defined, documented threat would belie the need to immunize the entire force. Any consideration of the “threat” must include both the lethality of the disease itself as well as the wherewithal and intent of bad actors to wield it as a weapon.

ANTHRAX, A DEADLY DISEASE

“Anthrax is an infectious disease caused by the spores of the bacterium, *Bacillus anthracis*.²⁶ There are three forms of the disease defined by how the spores enter the body: cutaneous (through the skin); gastrointestinal (by eating infected food), and inhalation (breathed into the lungs).²⁷ The disease is normally contracted by handling infected animal products, breathing in anthrax spores from those products, or eating infected, undercooked meat.²⁸ Of

the three forms, inhalation anthrax is the most deadly with a fatality rate in excess of 80% in unvaccinated populations.²⁹

A person exposed to anthrax spores through inhalation will first exhibit cold and flu like symptoms within seven to 42 days, including sore throat, fever, and muscle aches.³⁰ Follow on symptoms for untreated persons include coughing, chest pain, and shortness of breath.³¹ Post-exposure treatment includes antibiotics and vaccine; post-infection treatment dictates a 60-day course of antibiotics.³²

Anthrax may also be weaponized to disperse spores across the battlefield. The lethality and efficacy of anthrax as a weapon was demonstrated in 2001 in the United States in an act of domestic terrorism when letters contaminated with anthrax powder caused 22 cases of anthrax infection, resulting in deaths of five of eleven of the victims infected through inhaling the spores.³³ In addition, in 1993 then USSR President Boris Yeltsin confirmed what has long been suspected by the West that the 1979 deaths of 68 people in the industrial city of Sverdlovsk were due to an accidental aerosol release of anthrax spores into the atmosphere by a nearby Soviet military facility – spores that were inhaled by an unsuspecting, unvaccinated populace.³⁴

ANTHRAX AS A BIOLOGICAL WEAPON

According to DoD, anthrax, a biological agent, is easy to weaponize requiring little in the way of sophisticated scientific equipment, expertise, or technology.³⁵ Anthrax spores are incredibly hearty and stable allowing for resistance to certain climatic conditions and ease of long-term storage.³⁶ Significantly, anthrax spores are colorless, odorless, and tasteless. These characteristics enable dispersion on the battlefield or rear areas to occur without easy detection until the onset of symptoms. From a biological warfare perspective, it is the poor-man's/poor country's weapon of mass destruction.

The potential for use of anthrax or any number of other agents as a biological weapon is borne out by a former deputy chief of the former Soviet Union's Biopreparat (the biological weapons program), Dr. Ken Alibek, who defected to the United States in 1992.³⁷ Alibek describes the former Soviet Union's biological weapons programs as huge, with over 60,000 people involved in research, development and production activities as late as the early 1990s.³⁸ Soviet doctrine, according to Alibek, was to use biological weapons such as anthrax at the strategic and operational level on a massive scale to disrupt and degrade civilian and military capabilities.³⁹ In order to execute this doctrine, Alibek confirmed that the Soviet Union stockpiled hundreds of tons of anthrax (along with dozens of tons of smallpox and plague).⁴⁰ At

one point the Soviet Union had four major anthrax production facilities with one facility able to produce 300 tons of anthrax during a 250-day manufacturing period.⁴¹

With the collapse of the Soviet Union in 1992, Russian President Yeltsin decreed the end to all biological weapons development and directed the destruction of existing stockpiles. While some destruction did occur, Alibek questions whether the old Soviet programs have been completely dismantled.⁴² The end of the Cold War and generally friendly relations between the United States and Russia ought to allow those in DoD concerned with the biological threat to sleep easier at night. The problem, however, is not only whether all the old stockpiles have been destroyed, but also whether those that have not been are properly safeguarded. Additionally, the issue of technological and biological weapons expertise in the Russian scientific community is cause for legitimate concern. Alibek validates these concerns when he relates that informed sources within Russia have told him how easy it is to steal from biological weapons facilities and how groups of scientists are willing to sell products and techniques to the highest bidders.⁴³ Alibek confirms that many scientists who worked in the old biological weapons programs have left Russia, some likely ending up in Iran and other Middle Eastern countries.⁴⁴

This raises the next questions: what countries might possess anthrax as a biological weapon and, which might be hostile to the United States? In this regard, in sworn testimony before Congress, then Deputy Secretary of Defense Hamre said, "The primary issue is there are 10 countries in this world that have already taken the steps to put anthrax in a bomb or in a missile and to launch it against our troops for one purpose, to kill them."⁴⁵ AVIP in May 2003 refined this number to seven countries, including Iran, Libya, and North Korea, but not including a potential host of transnational terrorist groups.⁴⁶ Left off this list in 2003, but included among Dr. Hamre's ten countries was Iraq.⁴⁷ Currently, the hunt for Saddam Hussein's weapons of mass destruction programs continues in Iraq.

THE VACCINE

If anthrax the disease is lethal, if it is easily spread as part of a weapons system, and if military adversaries of the United States have the wherewithal to deploy such a weapon, then it appears prudent to take appropriate counter measures. DoD has determined that a vaccine, as part of a layered protective suite, is the best measure to thwart the threat to American forces. It is the vaccine, however, that has wrought the most concern about DoD's vaccination program.

ANTHRAX VACCINE ADSORBED

Medically speaking, vaccines serve as a type of medication to prevent infection by stimulating the human body's immune system to produce antibodies that, in turn, serve as a defense mechanism should the body become exposed to a threatening microbe.⁴⁸ The earliest vaccines have been around for centuries, but most research and development has taken place since the 1950s.⁴⁹ Significantly, vaccines have been successful in eradicating or controlling once wide-spread deadly diseases such as smallpox, diphtheria, and measles.⁵⁰

Such is the case with anthrax where at-risk persons—veterinarians, persons handling potentially infected animals, and certain lab workers—who have been vaccinated as a matter of course have been free of the disease for decades. According to the Food and Drug Administration (FDA), the only known means to protect and prevent against the onset of anthrax disease once exposed is to have been previously vaccinated with the anthrax vaccine.⁵¹ A vaccine suitable for human use was first developed in 1954 and, thereafter, went through a number of years of clinical testing in monkeys and humans, product improvement, and safety and efficacy testing.⁵² Ultimately, the National Institute of Health (NIH) approved a vaccine—anthrax vaccine adsorbed (AVA)—for general use in November 1970, issuing a license to the sole manufacturer, the Michigan Department of Public Health.⁵³ Two years later, the Department of Health, Education and Welfare transferred responsibility of regulation of biologic products from NIH to the FDA at which time the FDA began a review of all licensed biologics.⁵⁴ As part of this review, the licensed anthrax vaccine (AVA) was re-checked for safety, effectiveness, and labeling.⁵⁵ The FDA review panel concluded that AVA was “safe, effective, and not misbranded.”⁵⁶

The Center for Disease Control describes AVA as made from “a cell-free filtrate of *B. anthracis* culture that contains no dead or live bacteria.”⁵⁷ Consequently, it is not possible for a person vaccinated with AVA to contract anthrax disease from the vaccine itself. The manufacturer's approved label for licensed AVA mandates three subcutaneous injections of 0.5ml of vaccine given two weeks apart followed by injections in the same amount and means at six, twelve and eighteen months.⁵⁸ In a letter to DoD dated September 29, 1999, the FDA made clear that full immunization requires full dosing of all six shots on schedule in accordance with the product label.⁵⁹

If the FDA, as the federal regulator of biologic products and vaccines, has determined the vaccine safe, effective and not mislabeled, why has there been such a push back from service members about subjecting themselves to immunization? Aside from the issue of trust and some concerns about injection-site reactions and adverse events, the primary attack has been against

how the vaccine is manufactured by the sole manufacturer and holder of the FDA license to produce AVA—BioPort Corporation.

THE MANUFACTURER

In 1970 the FDA licensed the manufacture of AVA to the Michigan Department of Public Health (MDPH), a state-owned biologics lab that was first built in 1925.⁶⁰ During the ensuing decades MDPH produced a number of vaccines that contributed to public health: diphtheria, whooping cough, typhoid, tetanus, smallpox, and rabies.⁶¹ MDPH began serious research on the anthrax vaccine in 1965 at the request of the federal government after Merck, a pharmaceutical company, ceased production of its trial vaccine due, in part, to lack of a significant enough demand in the market.⁶² After receiving its license in 1970, MDPH distributed about 68,000 doses of AVA through 1989 primarily to at-risk persons most likely to come in contact with anthrax spores.⁶³ Thereafter, beginning in 1990, MDPH increased production of AVA to meet the needs of DoD immediately before and during the first Gulf War when Iraq was thought to possess significant capability to weaponize and deploy anthrax on the battlefield.⁶⁴ DoD estimates that between 250,000 and 300,000 doses of AVA purchased from MDPH were administered to about 150,000 service members who participated in Operation Desert Storm in 1991.⁶⁵

By the mid-1990s the State of Michigan decided to stop making vaccines due in part to the increased regulatory requirements imposed by the FDA for the manufacture of biologic products.⁶⁶ In 1996, the facility was turned over to a newly created state agency—Michigan Biologic Products Institute (MBPI)—for the sole purpose of privatizing the production of vaccine.⁶⁷ Prior to selling the vaccine facility and assets, MBPI executed an Army contract in 1997 to maintain the current equipment and facilities as well as the stockpile of AVA for national security purposes.⁶⁸ In January 1998, the state agreed to cease production of AVA in order to begin long overdue renovations needed to meet the increased production schedule for AVA; DoD signed a contract to fund most of these renovations.⁶⁹

BioPort Corporation was founded in 1998 with a view toward bidding on the sale of the assets of MBPI from the State of Michigan.⁷⁰ After an open bid process, BioPort Corporation, the only United States company to bid on the facility, prevailed, taking possession on September 4, 1998, while renovations were still on-going.⁷¹ Shortly thereafter DoD executed a new contract with BioPort for AVA production in order to meet requirements for the recently announced force-wide vaccination program.⁷² BioPort remains the only holder of an FDA

license to produce anthrax vaccine. Unfortunately for BioPort and DoD, BioPort became the lightning rod for opponents of DoD's anthrax vaccine immunization policy.⁷³

Upon taking possession of MBPI's facilities and assets in September 1998, including the FDA-license to make anthrax vaccine, BioPort immediately faced two competing forces. The first was DoD's immediate need for vaccine to execute the announced force-wide vaccination policy at a time when the production line was shut down for renovation. The second was the FDA's very stringent standards for achieving compliance in accord with current good manufacturing practices to re-open and begin manufacturing.⁷⁴ Specifically, before BioPort could begin shipment of any vaccine made in the renovated facility, they needed the FDA to approve their submitted Supplement to their Biologics License Application (BLA).⁷⁵ Accordingly, only AVA made prior to January 1998, when renovations began, that had not passed expiration dates while in the stockpile could be used by DoD. BioPort was under enormous pressure to complete all tasks as quickly as possible to secure FDA approval of the BLA Supplement while undergoing intense scrutiny by the FDA.

By any measure, BioPort struggled early on in meeting timelines for FDA approval suffering cash flow problems and calling into question management's capability and the expertise of its employees.⁷⁶ This in turn led DoD to re-structure contracts to ensure BioPort could meet payroll and hire the necessary consultants to guide them through the FDA approval process.⁷⁷ It was not until December 2001 that the FDA finally approved BioPort's BLA supplement, some three years after purchase and the announcement of DoD's vaccination policy.⁷⁸ Once approved, BioPort was able to ship AVA produced as part of the process validation component of the FDA-approval process and begin full scale manufacturing to meet DoD's needs.

BioPort's struggles as the lone manufacturer of anthrax vaccine had consequences for DoD's program. Specifically, as the stockpile of available vaccine dwindled, DoD was forced to implement a series of temporary "slowdowns" that kept narrowing the pool of service members required to receive anthrax shots to those deemed most at risk.⁷⁹ The program was first "narrowed" to apply to only those service members on orders for Korea or Southwest Asia for any period of time,⁸⁰ then only to those going to those areas for at least 30 days,⁸¹ and ultimately only to those persons going to Southwest Asia.⁸² Each slowdown tended to fuel anti-vaccination sentiment and raise questions about BioPort and the program. When BioPort was approved for full production, DoD's needs for AVA could be met. Notwithstanding, the current Secretary of Defense, Donald Rumsfeld, determined that force-wide vaccination may not be necessary and, instead, ordered on June 28, 2002, that only those service members deemed to

be at risk (defined as deploying to a high threat area for more than fifteen days) would begin or continue where they left off the six-shot vaccination regimen.⁸³

SAFETY AND EFFICACY

Despite the FDA's and CDC's repeated assertions that the anthrax vaccine was safe and effective, critics of the vaccine remain unconvinced. The opposition was so vociferous that the Congress directed DoD to contract with the National Research Council for the Institute of Medicine (IOM) to conduct an independent examination of the safety and efficacy of AVA.⁸⁴ To no surprise of DoD's proponents of the program who had defended it for over three years, the IOM released a favorable report in March 2002.⁸⁵ The report answered the seminal questions of "Is it Safe?... Does it Work" in the affirmative, qualifying its findings with a recommendation that research continue to develop a better vaccine that requires fewer shots.⁸⁶

With BioPort fully licensed in a renovated facility, with the resumption of immunization of service members deploying to high threat areas, and with the IOM report confirming DoD's long-standing defense of the vaccine, all issues seemed to be resolved for continuation of a well-intended program for the foreseeable future. The IOM report also seemed to quell Congressional concerns about the program that over the previous four years produced 15 hearings, 11 of which before the very partisan House Government Reform Committee, and the introduction of three bills that would have gutted the program.⁸⁷ Unfortunately for DoD, some legal issues have yet to be played out.

THE LEGAL ISSUES

Army Regulation 600-20 sets forth the criteria by which immunizations may be given involuntarily using the minimum force necessary.⁸⁸ Counseling, education, and a direct order that is refused must precede a decision that may only be made at the General Court-Martial Convening Authority level (or designated representative) that imminent threat conditions exist that mandate involuntary vaccination.⁸⁹ Ordinarily, the regulation contemplates that soldiers will not be involuntarily vaccinated.⁹⁰ Such has been the case with the AVIP where no forced vaccinations have taken place.⁹¹ However, inasmuch as the AVIP was and is mandatory for designated persons deploying to high threat areas, enforcement for those who refuse to submit to vaccination is a matter of discipline left to the discretion of the appropriate commander as contemplated by the Uniform Code of Military Justice (UCMJ).

AVIP tracks anthrax vaccination refusals and separations and reports that data to Congress. Prior to August 15, 2000, AVIP tracked specific military justice actions for anthrax vaccination refusals showing that some 441 active and reserve component service members

had been offered nonjudicial punishment under the provisions of Article 15, UCMJ, with 51 of those same individuals opting for trial by courts-martial.⁹² Since April 2000, AVIP only tracks separations (courts-martial or administratively) for the purpose of reporting to Congress.⁹³ Only nine additional service members have been separated from active or reserve component service since then.⁹⁴ The majority of persons who refused a direct military order to submit to the vaccination did so professing a belief that the vaccine would be harmful to them and that the order given was not lawful. No such defense has prevailed at the court-martial or military appellate court level.⁹⁵ To put these less than 500 refusals in context, the total number of service members vaccinated and total number of shots given must be considered. According to AVIP, since program inception over 1,035,000 service members have been vaccinated receiving over 3.7 million doses of vaccine.⁹⁶

The one legal issue that has been the constant theme of military accused at trial and other AVIP opponents is that the use of AVA by DoD to protect against inhalational exposure renders the use experimental.⁹⁷ In essence, the assertion is that the vaccine is being used “off-label” and is unapproved for its applied use. As such, the logic goes that the vaccine must be treated as an investigational new drug (IND). In most instances, any vaccine used as an IND requires the informed consent of the “patient.”⁹⁸ If applied literally to the AVIP, DoD could no longer make vaccination mandatory and punish those who refuse to take the shots.

FDA and DoD have consistently maintained that AVA, as licensed, provides protection against all forms of anthrax regardless of route of exposure and that the use of the vaccine to implement the AVIP is not experimental, is not being used off-label, and is not an IND. Accordingly, DoD remains adamant that the law does not require obtaining informed consent from service members. Unfortunately for DoD, what can only be described as the first “victory” for opponents of the AVIP came on December 22, 2003, when U.S. District Court Judge for the District of Columbia, Emmett Sullivan, issued a preliminary injunction on behalf of six plaintiffs directing DoD to stop mandatory anthrax vaccinations.⁹⁹ For the first time since inception of the AVIP, a court of competent authority determined that DoD’s use of the vaccine was experimental and being used for an unapproved purpose, focusing on the aspect of cutaneous versus inhalational exposure.¹⁰⁰ As a result, on December 23, 2003, DoD suspended all anthrax shots under the AVIP until the legal situation could be clarified.¹⁰¹

Significantly, on December 30, 2003, the FDA issued its final rule for all biologic products that had been pending as an interim rule since 1985, making it clear that the FDA does not regard AVA as investigational for protection against anthrax, regardless of route of exposure.¹⁰² The Justice Department immediately filed a motion requesting Judge Sullivan to vacate the

injunction.¹⁰³ Plaintiffs' lawyers responded to press inquiries about the FDA rule- making by asserting that the rule as published only makes the DoD's use of the vaccine proper from the date of the rule forward.¹⁰⁴ On January 7, 2004, Judge Sullivan vacated the temporary injunction¹⁰⁵; DoD re-started the AVIP immediately thereafter.¹⁰⁶ The law suit on behalf of the six plaintiffs, however, will continue. The ultimate result of this and similar litigation could significantly impact DoD's mandatory force health protection posture.

Should the plaintiffs prevail in stopping DoD from mandatory vaccination by requiring informed consent before use, DoD could seek to invoke Presidential authority to waive informed consent for investigational drugs based on serious threats using the procedures set forth in Executive Order 13139 and Title 10, US Code, Section 1107.¹⁰⁷ The *Army Times* in an editorial calling for a halt to the AVIP reported that DoD officials said "it was unlikely that they would seek a presidential waiver."¹⁰⁸

CONCLUSIONS

Maintaining combat power to accomplish the military mission is one of the most significant responsibilities of our leadership. An important component of that force protection is maintaining and sustaining the health of the force. Protection of the force from diseases—both naturally occurring and manmade biological weapons—may be the single most important health protection measure DoD can take. The scientific and medical communities have developed vaccines that have proven effective in immunizing humans from many diseases that have plagued mankind for centuries, including anthrax.

Various intelligence and threat assessments have led certain combatant commanders, then the Joint Chiefs, and ultimately the civilian leadership of DoD to the conclusion that a number of the United States' adversaries and non-state terrorist groups have both the capability and will to use anthrax against United States forces. Advised by medical and scientific experts that an FDA-licensed vaccine had been successfully used for decades in the United States, these leaders rightly concluded that it would be irresponsible to send service members into harms way and potential exposure to anthrax without preventive vaccination.

Making vaccination mandatory generated concern, anxiety, and fear among some service members and energized Congress to question publicly the safety of the vaccine and credibility of the threat. Every "refusal" instantly became a media event. Internet sites, such as "AnthraxNo@one-list.com," further fueled rumors and, in some cases, misinformation about the vaccine's safety record and BioPort's struggle to achieve FDA approval. Initially, every service member who suffered from some ailment who previously had begun the anthrax vaccination

series was encouraged by AVIP opponents to believe that the vaccine was the source of the problem. Although adverse events from the anthrax vaccine compared very favorably with a host of other vaccines, such as the influenza vaccine, the naysayers tended to “demonize” the anthrax vaccine as the root of all problems even though ailments suffered by those vaccinated remained virtually the same as those in the unvaccinated population.¹⁰⁹

As the number of service members vaccinated increased without any disproportional increase in adverse events, AVIP opponents seized upon a legal device to end mandatory vaccination. The lawsuits maintained that the vaccine had never been licensed and approved for use to protect against exposure to anthrax spores through the lungs, the very threat DoD sought to counter with the AVIP. As asserted by opponents of AVIP, the vaccine was being used off-label thereby making it an investigational new drug requiring informed consent.

Allowing individual service members to choose to be vaccinated and protected or not is incompatible with how the Nation’s military fights and wins on the battlefield. The United States military fights as part of team with each individual dependent on the other team member. No commander can be expected to prosecute the war with the uncertainty that the unvaccinated part of the force would become combat casualties in the event of an anthrax bioweapon attack. Those sick and diseased persons would not only put their fellow service members at risk, but also the mission itself. A force health protection program in the face of a real threat simply cannot be left to the discretion of individual service members without jeopardizing strategic objectives.

In hindsight, DoD was unprepared for the magnitude of opposition against the AVIP and the manner in which the issue became politicized. Although AVIP and the Services did a tremendous job producing educational materials to address the myths and misinformation about the vaccine, much of what was done was reactive and not proactive. DoD was also naïve or, at least, overly optimistic regarding the time and effort it would take for BioPort to be approved by the FDA to begin manufacturing new lots of vaccine necessary to execute the program as envisioned. Because there was only one source for AVA in the United States, BioPort, became the albatross that hung heavily around the AVIP’s neck for years. DoD also underestimated at best or failed to appreciate at worst how the legacy of government actions from generations past—Gulf War Syndrome, Agent Orange, Atomic Veterans, etc.—would inhibit the level of trust that must exist between leaders and the led.

Notwithstanding the foregoing, the bottom line for the AVIP is that until a “better” vaccine is developed, the current FDA-approved vaccine is the best defense and protection that exists today for service members facing the deadly threat of anthrax bioweapons.

RECOMMENDATIONS

So long as a legitimate threat exists, DoD must continue all efforts to stave off the legal machinations and political pressures to halt the AVIP. The first step requires DoD to defend aggressively all law suits designed to halt the AVIP or to make vaccination voluntary. In the event that the court challenges succeed, DoD should invoke the Presidential waiver provisions of EO 13139. The continued presence of forces in the Persian Gulf and Korea and the on-going global war on terrorism warrant such consideration in light of the threat.

In light of the production unpredictability issues that surfaced with having a single commercial source for AVA, DoD must aggressively pursue a government-owned contractor-operated (GOCO) vaccine manufacturing facility that meets FDA approval to ensure the availability of future vaccines that may not have mass market commercial appeal. In conjunction with pursuing a GOCO, DoD must continue to fund the research and development of a "better" anthrax vaccine and other vaccines based on future biowarfare threats.

Last, DoD must come to grips with the legacy of the past and seek to rebuild trust in government with affected veterans and, in turn, today's Soldiers, Sailors, Airmen, Marines, and Coast Guardsmen. Open and honest dialogue, acknowledgment of responsibility where appropriate, and compensation must underpin this effort. Continued education of the force and Congress on the nature of the threat and strong leadership will set the foundation for future force health protection initiatives.

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ENDNOTES

¹ Joint Publication 3-0, *Doctrine for Joint Operations*, defines force protection as those actions taken to prevent or mitigate hostile actions against Department of Defense personnel (to include family members), resources, facilities, and critical infrastructure.

² To understand the potential political fall out from failures to protect the force, one need only consider events such as the bombing of the Marine Corps barracks in Lebanon, the bombing of Khobar Towers in Saudi Arabia, the bombing of the USS Cole in Yemen, and the unsuccessful raid by Army Rangers and Special Forces into Mogadishu, Somalia. Arguably, each case materially altered U.S. strategy and, in some instances, the careers of politicians and military officers.

³ Anthrax Vaccine Immunization Program, *Information about the Anthrax Vaccine and the Anthrax Vaccine Immunization Program (AVIP)*, (Washington, D.C., 21 May 2003); available from http://www.anthrax.mil/media/pdf/info_paper.pdf; Internet; accessed 20 December 2003.

⁴ Bryan Bender, "Pentagon to Vaccinate All Troops Against Anthrax," *Defense Daily* (16 December 1997): Vol. 197, Iss. 51 [database on-line]; available from ProQuest; accessed 20 December 2003.

⁵ Ibid.

⁶ Secretary of Defense William S. Cohen, "Implementation of the Anthrax Vaccination Program for the Total Force," memorandum for Secretaries of the Military Departments, Chairman of the Joint Chiefs of Staff, Under Secretaries of Defense, Assistant Secretaries of Defense, DoD General Counsel, and DoD Inspector General, Washington, D.C., 18 May 1998. Secretary Cohen set four conditions for approval: (1) supplemental testing of vaccine lots in the stockpile to ensure potency, purity, sterility, and safety, consistent with FDA standards; (2) approval of the Services' implementation plans for execution and communication; (3) implementation of a system for fully tracking anthrax vaccinations; and (4) review of health and medical aspects of the program by an independent expert.

⁷ Ibid.

⁸ Ibid. The Executive Agent functions set forth by Secretary Cohen included: manage and administer the overall program; serve as focal point for the submission of information from the Services relating to adverse reactions and vaccine projected program requirements; monitor the Services' implementation of the program; and execute the Army's implementation plan.

⁹ COL Randy Randolph, Executive Officer, Office of The Army Surgeon General, gaston.randolph@us.army.mil, "Re: Need Some Help, Please," electronic mail message to COL Don Curry, donald.g.curry@us.army.mil, 17 February 2004.

¹⁰ Anthrax Vaccine Immunization Program, "Desk Reference on Vaccines and Immunity," (Washington, D.C., 12 November 1999); available from http://www.anthrax.mil/media/pdf/desk_ref.pdf; Internet; accessed 20 December 2003.

¹¹ Department of Veterans Affairs, *Combined Analysis of the VA and DoD Gulf War Clinical Evaluation Programs* (Washington, D.C., September 2002); available from [http://www.va.gov/ulwardocs/combined Registryanalysis2_.pdf](http://www.va.gov/ulwardocs/combined%20Registryanalysis2_.pdf); Internet; accessed 22 December 2003.

¹² Ibid.

¹³ Ibid. Many explanations have been offered and explored as cause or causes for the syndrome including low-level exposure to chemical weapons; use of DEET as an insect repellent; use of pyridostigmine bromide pills; inhalation of oil-well fire smoke; vaccination for anthrax, botulinum, influenza, typhoid, and tetanus; exposure to depleted uranium; and stress.

¹⁴ Institute of Medicine, "Gulf War and Health: Volume 1, Depleted Uranium, Sarin, Pyridostigmine Bromide, Vaccines," 2000; available from http://www.gulflink.osd.mil/iom_13sep00.pdf; Internet; accessed 20 December 2003.

¹⁵ Department of Veteran Affairs, *Agent Orange: Information for Veterans Who Served in Vietnam* (Washington, D.C., July 2003); available from <http://www1.va.gov/agentorange/docs/AO1B10-49JUL03.pdf>; Internet; accessed 22 December 2003.

¹⁶ Ibid.

¹⁷ Ibid.

¹⁸ Ibid. These diseases include chloracne (a skin disorder), certain nerve disorders, type 2 diabetes, numerous cancers, and certain birth defects.

¹⁹ Department of Defense News Release, "DoD Releases Five Project 112 SHAD Fact Sheets," 31 October 2002; available from <http://www.projectshad.org/>; Internet; accessed 22 December 2003.

²⁰ Ibid.

²¹ Ibid.

²² Department of Energy, *Advisory Committee on Human Radiation Experiments* (Washington, D.C., February 1995); available from <http://tis.eh.doe.gov/ohre/roadmap/achre/index.html>; Internet; accessed 22 December 2003.

²³ Ibid.

²⁴ Ibid.

²⁵ Anthrax Vaccine Immunization Program, "The Threat," undated; available from <http://www.anthrax.osd.mil/threat/topChoice.asp>; Internet; accessed 20 December 2003.

²⁶ Food and Drug Administration, "Anthrax," undated; available from <http://www.fda.gov/cber/vaccine/anthrax.htm>; Internet; accessed 20 December 2003.

²⁷ Ibid.

²⁸ Center for Disease Control, "Anthrax: What You Need to Know," undated; available from <http://www.bt.cdc.gov/agent/anthrax/needtoknow.asp>; Internet; accessed 20 December 2003.

²⁹ FDA, "Anthrax."

³⁰ CDC, "Anthrax: What You Need to Know."

³¹ Ibid.

³² Ibid.

³³ Kristen Weir, "Anthrax: Year One," *Current Science*, 3 January 2003, 8.

³⁴ "New Evidence in 1979 Soviet Anthrax Deaths," *Science* (19 March 1993): 1698 [database on-line]; available from ProQuest; accessed 20 December 2003.

³⁵ AVIP, *Information about the Anthrax Vaccine and the Anthrax Vaccine Immunization Program (AVIP)*.

³⁶ Ibid.

³⁷ Bill Patrick and Ken Alibek, "Interviews with Biowarriors," undated; available from http://www.pbs.org/wgbh/nova/bioterror/biow_alibek.html; Internet; accessed 26 December 2003.

³⁸ Ken Alibek, "Terrorist and Intelligence Operations: Potential Impact on U.S. Economy," 20 May 1998; testimony before the Joint Economic Committee, U.S. Congress; available from <http://www.house.gov/jec/hearings/intell/alibek.htm>; Internet; accessed 26 December 2003.

³⁹ Ibid.

⁴⁰ Ibid.

⁴¹ Patrick.

⁴² Alibek, "Terrorist and Intelligence Operations: Potential Impact on U.S. Economy."

⁴³ Patrick.

⁴⁴ Ken Alibek, "Preparing for the Range of Bioterrorism Possibilities," 17 October 2001; available from <http://cnn.community.printthis.clickability.com/pt/cpt?action=cpt&title=CNN>; Internet; accessed 26 December 2003.

⁴⁵ Congress, House of Representatives, Committee on Armed Services, Subcommittee on Military Personnel, *Department of Defense Anthrax Vaccine Immunization Program*, 106th Cong., 1st sess., 30 September 1999, 21.

⁴⁶ AVIP, *Information about the Anthrax Vaccine and the Anthrax Vaccine Immunization Program (AVIP)*.

⁴⁷ In the early 1990s, the United Nations Special Commission (UNSCOM) found evidence that Iraq had an extensive biological weapons program, including anthrax-filled weapons. UNSCOM also found evidence that Iraq had conducted air dispersal tests using an anthrax stimulant. AVIP, "The Threat."

⁴⁸ AVIP, "Desk Reference on Vaccines and Immunity."

⁴⁹ Ibid.

⁵⁰ Ibid.

⁵¹ FDA, "Anthrax."

⁵² Ruth K. Miller, "Informed Consent in the Military: Fighting a Losing Battle Against the Anthrax Vaccine," *American Journal of Law and Medicine* 28 (2002): 325 [database on-line]; available from ProQuest; accessed 20 December 2003.

⁵³ Margaret M. Dotzel, Associate Commissioner for Policy, Food and Drug Administration, letter to Mr. Russell Dingle, 28 August 2002; available from <http://www.fda.gov/ohrms/dockets/daileys/02/Sep02/091102/80027a9f.pdf>; Internet; accessed 20 December 2003.

⁵⁴ Ibid.

⁵⁵ Ibid.

⁵⁶ Ibid.

⁵⁷ Center for Disease Control, "Control and Prevention," 15 December 2000; available from <http://cdc.gov/mmwr/preview/mmwrhtml/rr4915a1.htm>; Internet; accessed 28 December 2003.

⁵⁸ Kathryn C. Zoon, Director, Center for Biologic Evaluation and Research, Food and Drug Administration, letter to Dr. Sue Bailey, 29 September 1999; available from <http://www.anthrax.osd.mil/media/pdf/fda.response.pdf>; Internet; accessed 28 December 2003.

⁵⁹ Ibid.

⁶⁰ BioPort Corporation, "BioPort History," undated; available from <http://www.bioport.com/default.asp>; Internet; accessed 29 December 2003.

⁶¹ Ibid.

⁶² Ibid.

⁶³ Ibid.

⁶⁴ Ibid.

⁶⁵ Ibid.

⁶⁶ Ibid.

⁶⁷ Ibid.

⁶⁸ Ibid.

⁶⁹ Ibid.

⁷⁰ Ibid.

⁷¹ Ibid.

⁷² Ibid.

⁷³ Prior to the sale to BioPort by the State of Michigan, the FDA had conducted rigorous inspections of the plasma and rabies vaccine production facilities (not the AVA production line) resulting in a warning letter in 1995 and a Notice of Intent to Revoke (NOIR) in March 1997 when follow up inspections showed that corrections had not be made as scheduled. The NOIR threatened to revoke Michigan's license to make vaccines absent immediate action. Michigan responded quickly with a Strategic Plan for Immediate Compliance within 30 Days. While subsequent action by Michigan satisfied the FDA that Michigan was making progress in meeting its compliance goals in the short term, the renovations were not completed prior to the sale to BioPort. AVIP, *Information about the Anthrax Vaccine and the Anthrax Vaccine Immunization Program (AVIP)*. The "warning letter" and NOIR, however, fueled barracks rumors and Internet myths about the safety, purity, and sterility of anthrax vaccine production for years.

⁷⁴ Dotzel.

⁷⁵ Ibid.

⁷⁶ Congress, Senate, Committee on Armed Services, *To Review the Department of Defense Anthrax Vaccine Immunization Program*, 106th Cong., 1st sess., 13 April 2000.

⁷⁷ Congress, House of Representatives, Committee on Armed Services, Subcommittee on Military Personnel, *Department of Defense Anthrax Vaccine Program (AVIP)*, 106th Cong., 2nd sess., 13 July 2000, 129.

⁷⁸ Dotzel.

⁷⁹ AVIP, *Information about the Anthrax Vaccine and the Anthrax Vaccine Immunization Program (AVIP)*.

⁸⁰ Under Secretary of Defense for Personnel and Readiness Rudy de Leon, "Change to Anthrax Vaccine Immunization Program (AVIP) Operational Procedure (One Day Policy)," memorandum for Secretaries of the Military Departments, Washington, D.C., 30 March 1999.

⁸¹ Deputy Secretary of Defense Rudy de Leon, "Temporary Slowing and Future Resumption of Anthrax Vaccine Immunization Program (AVIP)," memorandum for Chairman of the Joint Chiefs of Staff, Under Secretaries of Defense, Assistant Secretaries of Defense, DoD General Counsel, and DoD Inspector General, Washington, D.C., 17 July 2000.

⁸² MG Randall West, "Additional Temporary Slowing and Future Resumption of Anthrax Vaccine Immunization Program (AVIP)," memorandum for Vice Chief of Staff of the Army, Washington, D.C., 27 November 2000.

⁸³ Deputy Secretary of Defense Paul Wolfowitz, "Reintroduction of the Anthrax Vaccine Immunization Program (AVIP)," memorandum for Secretaries of the Military Departments, Chairman of the Joint Chiefs of Staff, Under Secretaries of Defense, Assistant Secretaries of Defense, DoD General Counsel, DoD Inspector General, Directors of Defense Agencies, and Commandant of the Coast Guard, Washington, D.C., 28 June 2002.

⁸⁴ Conference Report acc. 2002 DoD Appropriations Act, P.L. No. 106-79 (1999).

⁸⁵ The National Academies, "Anthrax Vaccine is Useful, but Shortcomings Underscore Need for Replacement," 6 March 2002; available from <http://www4.nationalacademies.org/news.nsf/isbn/0309083095?OpenDocument>; Internet; accessed 30 December 2003.

⁸⁶ Institute of Medicine, *The Anthrax Vaccine: Is It Safe? Does It Work?* (Washington, D.C.: National Academy Press, March 2002).

⁸⁷ When Secretary of Defense Cohen directed implementation of the AVIP, he was serving as part of the Democratic Clinton Administration. At that time and throughout the remainder of President Clinton's second term, Republicans held the majority in both the House of Representatives and the Senate. The House Government Reform Committee, chaired by Congressman Dan Burton (R-IN) and its National Security Subcommittee, chaired by Congressman Christopher Shays (R-CT), made the AVIP (a policy of the Clinton Administration) a point of intense, partisan scrutiny of the full committee and subcommittee (this despite DoD falling under the generally non-partisan House Armed Services Committee as the committee of primary jurisdiction). On 17 February 2002, the House Government Reform Committee adopted a report of the Shays Subcommittee after a vote along party lines condemning the AVIP (and the Administration that initiated it) as unnecessary. The report titled, *The Department of Defense Anthrax Vaccine Immunization Program: Unproven Force Protection*, and its recommendations to halt or make the program voluntary were not acted on by the DoD. As is now turns out, the concerns raised in the report about safety and efficacy of the vaccine to protect against inhalation anthrax have been contradicted by the independent IOM report.

⁸⁸ Department of the Army, *Army Command Policy*, Army Regulation 600-20 (Washington, D.C.: U.S. Department of the Army, 13 May 2002), 25.

⁸⁹ Ibid.

⁹⁰ Ibid.

⁹¹ COL John D. Grabenstein, RPh, PhD, Deputy Director, Military Vaccine Agency, telephone interview by author, 31 December 2003.

⁹² COL John D. Grabenstein, RPh, PhD, John.Grabenstein@otsg.amedd.army.mil, "Need Some Help, Please," electronic mail message to COL Don Curry donald.g.curry@us.army.mil, 31 December 2003.

⁹³ Ibid.

⁹⁴ Ibid.

⁹⁵ Jeffrey G. Hagler, Jeffrey.Hagler@us.army.mil, "No Known Military Cases Where AVIP Found Illegal," electronic mail message to COL Donald Curry, donald.g.curry@us.army.mil, 26 February 2004.

⁹⁶ Grabenstein, "Need Some Help, Please."

⁹⁷ The author draws this conclusion after reviewing numerous websites dedicated to stopping the AVIP, as well as, legal briefs and memoranda submitted in support of various law suits or criminal trials. For additional information, see generally the following websites: <http://www.dallasnw.quik/cyberella/index.htm>; <http://www.anthraxvaccine.org>; <http://www.avip2001.net/OfficialDocuments-files/Point.htm>; and <http://www.anthraxdeadlyshot.inthe.dark.com>.

⁹⁸ *Federal Food, Drug, and Cosmetic Act, Statutes at Large* sec. 505(i)(4).

⁹⁹ United States District Court for the District of Columbia, *John Does#, et al, v. Donald H. Rumsfeld, et al*, Civil Action No. 03-707 (EGS), 22 December 2003.

¹⁰⁰ Ibid.

¹⁰¹ Under Secretary of Defense for Personnel and Readiness David Chu, "Anthrax Vaccine Immunization Program (AVIP)," memorandum for Secretaries of the Military Departments, Chairman of the Joint Chiefs of Staff, Under Secretaries of Defense, Assistant Secretaries of Defense, DoD General Counsel, DoD Inspector General, Directors of Defense Agencies, and Commandant of the US Coast Guard, Washington, D.C., 23 December 2003.

¹⁰² Food and Drug Administration, "FDA Issues Final Rule and Final Order Regarding Safety and Efficacy of Certain Licensed Biological Products Including Anthrax Vaccine," 30 December 2003; available from <http://www.fda.gov/bbs/topics/NEWS/2003/NEW01001.html>; Internet; accessed 6 February 2004.

¹⁰³ Thom Shauker, "FDA Rules Shots Effective for Anthrax That Is Inhaled," *New York Times*, 31 January 2004; available from <https://www.us.army.mil/portal/jhtml/earlyBird/Dec20031231245461.html>; Internet; accessed 31 December 2003.

¹⁰⁴ Ibid.

¹⁰⁵ Jamie McIntyre, "Judge OKs Military Anthrax Vaccinations," CNN.Com, 8 January 2004, available from <http://www.cnn.com/2004/LAW/01/07/anthrax.military>; Internet; accessed 8 January 2004.

¹⁰⁶ Department of Defense, "Anthrax Vaccine Immunization Program Resumption," ALARACT Message, Washington, D.C., 8 January 2004.

¹⁰⁷ Executive Order 13139, "Improving Health Protection of Military Personnel Participating in Particular Military Operations," 30 September 1999; available from www.denix.osd.mil/denix/Public/Legislation/EO/notes54.html; Internet; accessed 20 December 2003.

¹⁰⁸ "No Longer a Threat," *The Army Times*, 5 January 2004.

¹⁰⁹ AVIP, *Information about the Anthrax Vaccine and the Anthrax Vaccine Immunization Program (AVIP)*.

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